II. AMENDMENTS TO THE CLAIMS

1. **(Currently amended)** A method of effectively treating benign prostatic hypertrophy in a human patient, comprising:

administering terazosin **or a pharmaceutically acceptable salt thereof** transdermally to [the] **a** human patient by applying a transdermal delivery system containing terazosin **or a pharmaceutically acceptable salt thereof** to the skin of **the** [a] patient, and maintaining said transdermal delivery system in contact with the skin of said patient for at least 3 days, said transdermal delivery system maintaining an effective mean relative release rate to provide a therapeutic blood level of said terazosin **or a pharmaceutically acceptable salt thereof** within 36 hours from the initiation of the dosing interval, and thereafter maintaining a therapeutic blood level until the end of at least the three-day dosing interval**; said system providing a mean relative release rate from about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of said terazosin or pharmaceutically acceptable salt thereof over the entire dosing interval**.

2. **(Original)** The method of claim 1, further comprising providing a mean relative release rate of terazosin from said transdermal delivery system to provide a plasma level of terazosin of at least about 1.0 ng/ml within about 6 hours after application of said transdermal delivery system onto the skin of the patient.

3. **(Original)** The method of claim 1, further comprising maintaining a plasma level of terazosin at steady-state from about 10 to about 60 ng/ml.

4. **(Original)** The method of claim 1, wherein said therapeutic plasma level is maintained from about 1.0 ng/ml to about 60 ng/ml during the dosing interval for said transdermal delivery system.

5. **(Cancelled)**

6. **(Original)** The method of claim 1, wherein said transdermal delivery system has a mean relative release rate from about 2.0 μg/hour/cm^2 to about 20 μg/hour/cm^2.

7. **(Original)** The method of claim 1, wherein said transdermal delivery system has a mean relative release rate from about 1.0 μg/cm^2/hr to about 30.0 μg/cm^2/hr at 24 hours;
from about 1.0 μg/cm^2/hr to about 28.0 μg/cm^2/hr at 48 hours; and
from about 1.0 μg/cm^2/hr to about 26.0 μg/cm^2/hr at 72 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of Ethanol:water.

8. **(Original)** The method of claim 1, wherein said transdermal delivery system provides an in-vitro cumulative amount of permeation of from about 52.8 μg/cm^2 to about 686.4 μg/cm^2 at 24 hours; from about 105.6 μg/cm^2 to about 1372.8 μg/cm^2 at 48 hours; and from about 158.4 μg/cm^2 to about 2059.2 μg/cm^2 at 72 hours, as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

9. **(Currently amended)** A method of effectively treating benign prostatic hypertrophy in a human patient, comprising:
administering terazosin **or a pharmaceutically acceptable salt thereof** transdermally to **a** [the] human patient by applying a transdermal delivery system containing terazosin **or a pharmaceutically acceptable salt thereof** to the skin of **the** [a] patient, and maintaining said transdermal delivery system in contact with the skin of the patient for at least 5 days, said transdermal delivery system maintaining an effective mean relative release rate to provide a

therapeutic blood level of said terazosin within three days from the initiation of the dosing interval, and thereafter maintaining a therapeutic blood level until the end of at least the five-day dosing interval; **said system providing a mean relative release rate from about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of said terazosin or pharmaceutically acceptable salt thereof over the entire dosing interval**.

10. **(Original)** The method of claim 9 wherein the plasma level of terazosin at 48 hours does not decrease by more than 30% over the next 72 hours.

11. **(Original)** The method of claim 9, further comprising maintaining an effective mean relative release rate of said transdermal delivery system to provide a substantially first order plasma level increase of terazosin from the initiation of the dosing interval until about 48 to about 72 hours after the initiation of the dosing interval; and thereafter providing an effective mean relative release rate to provide a substantially zero order plasma level fluctuation of terazosin until the end of at least the five-day dosing interval.

12. **(Original)** The method of claim 9, further comprising providing a mean relative release rate of terazosin from said transdermal delivery system to provide a plasma level of terazosin of at least about 1.0 ng/ml within about 6 hours after application of said transdermal delivery system onto the skin of the patient.

13. **(Original)** The method of claim 9, further comprising maintaining a plasma level of terazosin at steady-state from about 10 to about 60 ng/ml.

14. **(Original)** The method of claim 9, wherein said therapeutic plasma level is maintained from about 10 ng/ml to about 60 ng/ml during the dosing interval for said transdermal delivery system.

15. **(Original)** The method of claim 9, wherein said transdermal delivery system has a mean relative release rate from about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of said transdermal delivery system.

16. **(Original)** The method of claim 9, wherein said transdermal delivery system has a mean relative release rate from about 2.0 μg/hour/cm^2 to about 20 μg/hour/cm^2.

17. **(Original)** The method of claim 9, wherein said transdermal delivery system has a mean relative release rate from about 1.0 μg/cm^2/hr to about 30.0 μg/cm^2/hr at 24 hours;
from about 1.0 μg/cm^2/hr to about 28.0 μg/cm^2/hr at 48 hours; and
from about 1.0 μg/cm^2/hr to about 26.0 μg/cm^2/hr at 72 hours; and from about 1.0 μg/cm^2/hr to about 25.0 μg/cm^2/hr at 96 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

18. **(Original)** The method of claim 9, wherein said transdermal delivery system provides an in-vitro cumulative amount of permeation of from about 52.8 μg/cm^2 to about 686.4 μg/cm^2 at 24 hours; from about 105.6 μg/cm^2 to about 1372.8 μg/cm^2 at 48 hours; and from about 158.4 μg/cm^2 to about 2059.2 μg/cm^2 at 72 hours; and from about 211.2 μg/cm^2 to about 2745.6 μg/cm^2 at 96 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

Claims 19-21 **(Cancelled)**

22. **(Currently amended)** A transdermal delivery system containing terazosin or a pharmaceutically acceptable salt thereof which provides a mean relative release rate from about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of said [transdermal delivery system] **terazosin or pharmaceutically**

acceptable salt thereof over the entire dosing interval; a plasma level of terazosin of at least about 1.0 ng/ml by about 6 hours after application of said transdermal delivery system onto the skin of the patient; and a plasma level of terazosin at steady-state from about 10 to about 60 ng/ml.

23. **(Original)** The transdermal delivery system of claim 22, which provides a mean relative release rate from about 1.0 $\mu g/cm^2/hr$ to about 30.0 $\mu g/cm^2/hr$ at 24 hours;
from about 1.0 $\mu g/cm^2/hr$ to about 28.0 $\mu g/cm^2/hr$ at 48 hours; and
from about 1.0 $\mu g/cm^2/hr$ to about 27.0 $\mu g/cm^2/hr$ at 72 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

24. **(Original)** The transdermal delivery system of claim 22, which provides an in-vitro cumulative amount of permeation of from about 52.8 $\mu g/cm^2$ to about 686.4 $\mu g/cm^2$ at 24 hours; from about 105.6 $\mu g/cm^2$ to about 1372.8 $\mu g/cm^2$ at 48 hours; and from about 158.4 $\mu g/cm^2$ to about 2059.2 $\mu g/cm^2$ at 72 hours, as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

25. **(Original)** The transdermal delivery system of claim 22, comprising a backing layer which is impermeable to the active substance, a pressure-sensitive adhesive reservoir layer, and optionally a removable protective layer, the reservoir layer by weight comprising 20 to 90% of a polymeric matrix, 0.1 to 30% of a softening agent, 0.1 to 20% of terazosin base or of a pharmaceutically acceptable salt thereof and 0.1 to 30% of a solvent for the terazosin or salt thereof.

26. **(Cancelled)**

27. **(Original)** The transdermal delivery system of claim 22, which maintains a plasma level of terazosin at steady-state from about 10 to about 60 ng/ml.

28. **(Currently amended)** A transdermal delivery system comprising terazosin or a pharmaceutically acceptable salt thereof which maintains an effective mean relative release rate to provide a therapeutic blood level of said terazosin within three days from the initiation of the dosing interval, and thereafter maintaining a therapeutic blood level until the end of at least the five-day dosing interval**; said system providing a mean relative release rate from about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of said terazosin or pharmaceutically acceptable salt thereof over the entire dosing interval**.

29. **(Original)** The transdermal delivery system of claim 27, which has a mean relative release rate of terazosin effective to provide a plasma level of terazosin of at least about 1.0 ng/ml by about 6 hours after application of said transdermal delivery system onto the skin of the patient.

30. **(Original)** The transdermal delivery system of claim 27, which maintains a plasma level of terazosin at steady-state from about 10 to about 60 ng/ml.

31. **(Original)** The transdermal delivery system of claim 27, wherein said therapeutic plasma level is maintained from about 1.0 ng/ml to about 60 ng/ml during the dosing interval for said transdermal delivery system.

32. **(Original)** The transdermal delivery system of claim 27, wherein said transdermal delivery system has a mean relative release rate from about 1.0 μg/hour/cm^2 to about 30 μg/hour/cm^2 of said transdermal delivery system.

33. **(Original)** The transdermal delivery system of claim 27, wherein said transdermal delivery system has a mean relative release rate from about 1.0 $\mu g/cm^2/hr$ to about 30.0 $\mu g/cm^2/hr$ at 24 hours; from about 1.0 $\mu g/cm^2/hr$ to about 28.0 $\mu g/cm^2/hr$ at 48 hours; and
from about 1.0 $\mu g/cm^2/hr$ to about 26.0 $\mu g/cm^2/hr$ at 72 hours; and from about 1.0 $\mu g/cm^2/hr$ to about 25.0 $\mu g/cm^2/hr$ at 96 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

34. **(Original)** The transdermal delivery system of claim 27, wherein said transdermal delivery system provides an in-vitro cumulative amount of permeation of from about 52.8 $\mu g/cm^2$ to about 686.4 $\mu g/cm^2$ at 24 hours; from about 105.6 $\mu g/cm^2$ to about 1372.8 $\mu g/cm^2$ at 48 hours; and from about 158.4 $\mu g/cm^2$ to about 2059.2 $\mu g/cm^2$ at 72 hours; and from about 211.2 $\mu g/cm^2$ to about 2745.6 $\mu g/cm^2$ at 96 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell has a receptor chamber containing a 40:60 mixture of ethanol:water.

35. **(Original)** The transdermal delivery system according to claim 25, wherein the backing layer is composed of a flexible material.

36. **(Original)** The transdermal delivery system according to claim 25, wherein the backing layer is selected from the group consisting of a flexible material, an inflexible material, and an aluminum foil.

37. **(Original)** The transdermal delivery system according to claim 25, wherein the polymeric matrix is at least one of rubber, a rubber-like synthetic homo-, co- or blockpolymer, a urethane and silicone.

38. **(Original)** The transdermal delivery system according to claim 25, wherein the softening agent

is at least one of dodecanol, undecanol, octanol, a glycol and glycanol.

39. **(Original)** The transdermal delivery system according to claim 25, wherein the solvent is a monoester of a dicarboxylic acid.

40. **(Original)** The transdermal delivery system according to claim 25, wherein the solvent is at least one of monomethyl glutarate and monomethyl adipate.

41. **(Cancelled)**

42. **(Original)** The transdermal delivery system according to claim 25, wherein by weight the polymer is present in about 55%, the terazosin in about 10%, the solvent in about 10% and the softener in about 15%.

43. **(Original)** A transdermal delivery system according to claim 25, wherein the solvent is present in from about 25 to 100% the weight of the terazosin.

44. **(Original)** The transdermal delivery system according to claim 25, which also comprises a removable protective layer.

Claims 45-46 (**Cancelled**)

47. **(Original)** The transdermal delivery system according to claim 25, wherein the solvent has at least one acidic group.

48. **(Cancelled)**